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Joan Claybrook, President

Jan. 24, 2005

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20852

Re: Docket No. 2003F-0088 – "Irradiation in the Production, Processing, and Handling of Food"

Dear Sir/Madam:

Under the provisions of 21 CFR §12, Public Citizen is requesting a formal evidentiary public hearing for the purposes of revoking the Food and Drug Administration's Final Rule on Docket No. 2003F-0088 – "Irradiation in the Production, Processing and Handling of Food." (69 FR 76844-76847, Dec. 23, 2004)

Public Citizen is a national, non-profit, membership organization established in 1971 that advocates for consumer protection and for government and corporate accountability. We have identified and seek to present at a public hearing genuine and substantial issues containing evidence that raises material issues of fact and questions the rationale of this Rule.

(1) The FDA did not adequately account for the fact that within a beam of some nominal energy, there will be electrons of various energies. Since the energy of the incoming electron beam on the X-ray target is not monoenergetic, a significant portion of the beam may be higher than the nominal energy. If this occurs, neutron production can become larger and lead to undesired activation of food.

On page 51 of the petition, Figure 1 shows typical energy distributions for two different electron accelerators. The broad distribution around a dose of 10 MeV can be approximated as a Gaussian curve with full width at half maximum of 1.4 MeV. This gives a sigma of 0.6 MeV, meaning that 16 percent of the electrons would be greater than 10.6 MeV (1 sigma) and 2.8 percent greater than 11.2 MeV (2 sigma). In the published article of the same study that is included in the petition, the authors note that the accelerator settings corresponded to 7.5 MeV, but measurements and calculations indicated it was actually 8.1 +/- 0.8 MeV.[1] The 7.5 MeV was the "nominal" energy but the actual energy was 8.1 MeV, known to a precision of only plus or minus 10 percent.

[1] Gregoire, O., Cleland, M.R., Mittendorfer, J., Dababneh, S., Ehlermann, D.A., Fan, X., Kappeler, F., Logar, J., Meissner, J., Thayer, D.W. *Journal of Radiation Physics and Chemistry* 67(2): 169-183, 2003, p.177.

2003F-0088 HER 1 [redacted]

Using 7.5 MeV as the peak value of the Gaussian distribution used to approximate Figure 1 and taking a full width at half maximum of 1.05 MeV, we find a sigma of 0.45 MeV. This tells us that 16 percent of the electrons would have an energy level above 7.95 MeV and 2.8 percent above 8.4 MeV.

Did the experiments referenced in the petition adequately represent the effect of the high end of the distribution of energy? The experiments referenced in this petition did not measure the energy distribution of the electrons produced, only "an idea of the typical energy spread of an industrial linear accelerator."[2] In reality, the actual spread could have been broader or narrower. Realistic calculations must be performed that take into consideration the energy profile of the electron beam incident on the X-ray target and compared to data from experiments at the same (measured) incident energy and energy profile as the calculations before this application can be approved.

Public Citizen is requesting a formal evidentiary public hearing on this matter.

(2) In the Rule, the FDA presents no government or any other official standard to support its conclusion that 7.5 MeV X-rays will not induce hazardous levels of radioactivity in food, or present any other health hazards. The FDA cites no standards that detail "safe" levels of any induced radioactivity. In fact, we object to any agency decision to grant any petition that could result in any additional radiation level in treated food.

Public Citizen is requesting a formal evidentiary public hearing on this matter.

(3) The petitioner cites a paper that makes a calculation of the number of people who could get cancer by eating foods irradiated with 7.5 MeV X-rays – 0.08 per million.[3] The paper was written by prominent food irradiation researcher Ari Brynjolfsson.[4] The petitioner discusses the paper but omits the cancer calculation. The Rule does not cite the paper at all. Instead, the FDA cites an unpublished paper by the Oak Ridge National Laboratory that states that "it makes little sense" to calculate the risk of eating food with added radioactivity.[5] It is reckless for the FDA to approve the Rule without assessing cancer risks.

Public Citizen is requesting a formal evidentiary public hearing on this matter.

(4) Any additives created by this process, including, but not limited to, chemical byproducts or radioactivity, must be assessed for safety. The FDA did not comply with 21 CFR §170.22, which states: "Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals." This non-compliance includes not only the failure to conduct any animal experiments using foods irradiated under the provisions of this Rule, but also the failure to calculate a 100-to-1 safety factor or submit evidence that justifies the use of a different safety factor.

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[2] Gregoire et al p.175.

[3] Brynjolfsson, Ari. "Natural and Induced Radioactivity in Food." Proceedings of the International Conference on Future Nuclear Systems. *Global '99: Nuclear Technology – Bridging the Millenia.* Aug. 29 – Sept. 3, 1999, Jackson Hole, Wyo.

[4] Brynjolfsson has worked with many agencies and organizations over the past 40 years, including the World Health Organization, Food and Agricultural Organization, Codex Alimentarius Commission, and the International Atomic Energy Commission. He was Director of the U.S. Army's National Food Irradiation Program from 1971-1980. He has authored more than 100 published articles on food irradiation and related issues.

[5] Easterly, C. E. et al. "Assessment of Petition to Increase the Maximum X-Ray Energy to 7.5 MeV from the Value of 5.0 MeV for the Treatment of Food by Ionizing Radiation." ORNL-2003-1, Oak Ridge National Laboratory, Life Sciences Division, Oak Ridge, Tenn., 2003.

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(5) In its failure to conduct the assessments outlined in point 4, the FDA did not comply with 21 CFR §170.20, which states that "the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council."

Public Citizen is requesting a formal evidentiary public hearing on this matter.

(6) The FDA has not complied with 21 USC 348(c)(3)(A), which states: "No such [food additive] regulation shall issue if a fair evaluation of the data before the Secretary--(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man." Nor has the FDA complied with 21 CFR 170.3(i), which defines "safe" as "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

Public Citizen is requesting a formal evidentiary public hearing on this matter.

Taken together, these flaws in the FDA's Rule represent genuine and substantial issues containing evidence that raises material issues of fact and questions the rationale of the Rule. We request that a formal evidentiary public hearing be held at the earliest possible date and we urge you to revoke the approval of this petition.

Respectfully submitted,

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cc: Dr. Lester M. Crawford
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